IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Ashley, Robert	Examiner:	Susan Tran
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Confirmation No:	4179	Docket:	512-53 DIV/ CON II/RCE
Filed:	October 20, 2011	Dated:	February 22, 2013
For:	**Methods of Treating Acne**		

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Response to November 19, 2012 Final Office Action and Substance of February 7, 2013 Interview in Reply to February 19, 2013 Interview Summary

Sir:

In Reply to the November 19, 2012 Final Office Action and February 19, 2013 Interview Summary, applicant respectfully requests the instant Response be considered. Accompanying this Response is a Request for Continued Examination, a 37 C.F.R. §1.132 Declaration by Dr. Vasant Manna, a Terminal Disclaimer in view of US 7,232,572, and an Information Disclosure Statement.

Listing of the Claims begins on page 2 of this paper.

Remarks begin on page 5 of this paper.

Listing of the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Claims 1-20 (Cancelled).

21. (Previously Presented) A method for treating papules and pustules of rosacea in a human in need thereof, the method comprising

administering orally to said human doxycycline, or a pharmaceutically acceptable salt thereof,

in an amount that

(i) is effective to treat the papules and pustules of rosacea;

(ii) is 10-80% of a 50 mg dose of doxycycline; and

(iii) results in no reduction of skin microflora during a six-month treatment, without administering a bisphosphonate compound.

22. (Previously Presented) The method according to Claim 21, wherein said doxycycline is doxycycline monohydrate.

23. (Previously Presented) The method according to Claim 22, wherein said doxycycline monohydrate is administered in an amount of 40 milligrams.

24. (Previously Presented) The method according to Claim 23, wherein said doxycycline monohydrate is administered by sustained release.

25. (Previously Presented) A method according to Claim 24, wherein said doxycycline monohydrate is administered once a day.

26. (Previously Presented) The method according to Claim 22, wherein said doxycycline monohydrate is administered in a dose of 20 mg twice a day.

27. (Previously Presented) The method according to Claim 21, wherein said doxycycline, or a pharmaceutically acceptable salt thereof, is administered in an amount which provides a serum concentration in the range of about 0.1 to about 0.8 μg/ml.

28. (Previously Presented) A method for treating papules and pustules of rosacea in a human in need thereof, the method comprising

administering orally to said human doxycycline, or a pharmaceutically acceptable salt thereof,

in an amount that

(i) is effective to treat the papules and pustules of rosacea;

(ii) is 40-80% of a 50 mg dose of doxycycline; and

(iii) results in no reduction of skin microflora during a six-month treatment, without administering a bisphosphonate compound.

29. (Previously Presented) The method according to Claim 28, wherein said doxycycline is doxycycline monohydrate.

30. (Previously Presented) The method according to Claim 29, wherein said doxycycline monohydrate is administered in an amount of 40 milligrams.

31. (Previously Presented) The method according to Claim 30, wherein said doxycycline monohydrate is administered by sustained release.

32. (Previously Presented) A method according to Claim 31, wherein said doxycycline monohydrate is administered once a day.

33. (Previously Presented) The method according to Claim 29, wherein said doxycycline monohydrate is administered in a dose of 20 mg twice a day.

34. (Previously Presented) The method according to Claim 28, wherein said doxycycline, or a pharmaceutically acceptable salt thereof, is administered in an amount which provides a serum concentration in the range of about 0.1 to about 0.8 μg/ml.

35. (Previously Presented) A method for treating papules and pustules of rosacea in a human in need thereof, the method comprising

administering orally to said human doxycycline, or a pharmaceutically acceptable salt thereof, in an amount of 40mg per day, wherein the amount results in no reduction of skin microflora during a six-month treatment, without administering a bisphosphonate compound.

36. (Previously Presented) The method according to Claim 35, wherein said doxycycline is doxycycline monohydrate.

37. (Previously Presented) The method according to Claim 36, wherein said doxycycline monohydrate is administered by sustained release.

38. (Previously Presented) A method according to Claim 37, wherein said doxycycline monohydrate is administered once a day.

39. (Previously Presented) The method according to Claim 36, wherein said doxycycline monohydrate is administered in a dose of 20 mg twice a day.

40. (Previously Presented) The method according to Claim 35, wherein said doxycycline, or a pharmaceutically acceptable salt thereof, is administered in an amount which provides a serum concentration in the range of about 0.1 to about 0.8 μg/ml.

REMARKS

Claims 1-20 were previously cancelled. Claims 21-40 were previously added. Thus, Claims 21-40 are pending.

Substance of Interview

Applicant wishes to thank Examiner Susan Tran and Supervisory Patent Examiner Robert Wax for taking the time to discuss the instant application and for their courtesy during a personal interview with Ms. Cécile Cousin, Dr. Vasant Manna, Dr. Irving N. Feit and the undersigned on February 7, 2013. Dr. Manna stated to the examiners that he is a Medical Doctor with expertise in dermatology.

The Claimed Invention

During the interview applicant's representatives explained that the claimed invention is a method for treating papules and pustules of rosacea by oral administration of doxycycline (or a salt thereof). Papules and pustules occur on skin in facial rosacea. The doxycycline dose is expressed differently in each independent claim, i.e., 10-80% of a 50 mg, 40-80% of a 50 mg dose, and a 40 mg. The claims recite that all these doses result in no reduction of skin microflora during a six-month treatment. Applicant's representative emphasized that the treatment of papules and pustules of rosacea with such a dose was major development in the treatment of this condition, and was unknown in the prior art.

Obviousness Rejections under 35 U.S.C. §103(a) in View of Perricone and Pflugfelder

In the Final Office Action, the examiner maintained the obviousness rejections, under 35 U.S.C. §103(a), of Claims 21, 23, 25-28, 30, 32-35 and 38-40 over US 6,365,623 (hereinafter "*Perricone*") in view of US 6,455,583 (hereinafter "*Pflugfelder*"); of Claims 24, 25, 31, 32, 37 and 38 over *Perricone* in view of *Pflugfelder* and US 5,300,304; and of Claims

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